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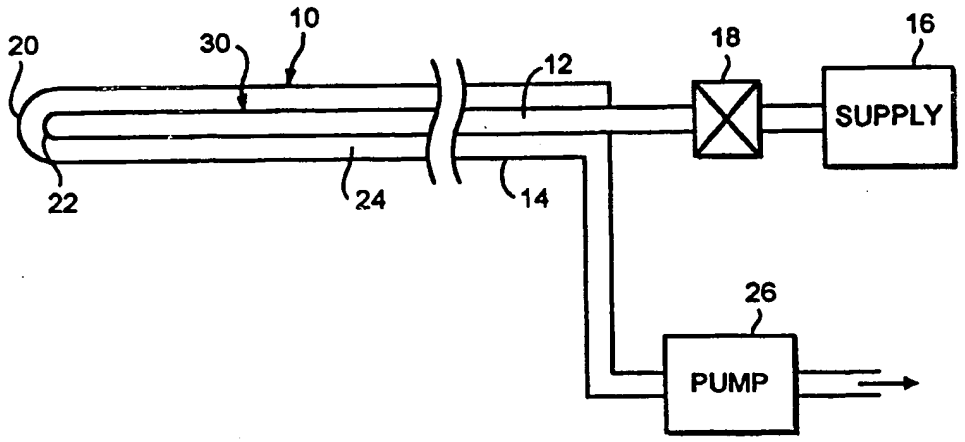

(57) Abstract

A cryosurgical catheter probe and method of operation are described. The probe comprises a Joule Thompson probe tip (20) joined to a catheter (10) which includes an inner supply conduit (12) and an outer exhaust conduit (14). A pump (26) is coupled to the downstream end of the exhaust conduit (14) to draw exhaust cryogen through the exhaust conduit. The pump (26) produces a negative pressure at the pump sufficiently great to produce a negative pressure in the exhaust path adjacent to the tip (20). The negative pressure reduces the chances of a leak, and also reduces the chances of cryogen escaping from the catheter into the patient's blood vessel if a leak does occur.

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ARRANGEMENT FOR COOLED PROBES

This invention relates to cooled probes, and in particular to probes for insertion into a human or animal body. The term "probe" is intended to be interpreted broadly, and to include devices such as catheters, and the like. In one form, the invention is particularly suitable for use in association with a cryosurgical catheter, but the invention is not limited exclusively to such use.

Cryosurgical devices generally use one of two mechanisms to achieve the desired cooling. Liquid cryogen devices rely on evaporation of a liquid cryogen, such as liquid nitrogen or liquid helium, to produce the cooling effect. Joule-Thompson devices rely on the Joule-Thompson effect to produce cooling by throttling of a high pressure gas, for example nitrous oxide (N_2O), through a small orifice. The present invention is especially suitable for Joule-Thompson effect systems.

A cryosurgical catheter having a Joule-Thompson cooled tip has been proposed in US-A-5078713. The catheter has a metal tip which is bonded to the end of the catheter. Within the catheter tube, a conduit delivers high pressure gas to the probe tip. After expansion, the gas exhausts through the catheter tube, in the space surrounding the delivery conduit.

Other catheter arrangements are described, for example, in GB-A-2283678, GB-A-2226497, EP-A-0655225 and DE-A-2332513.

Although of enormous potential in enabling a cryosurgical probe tip to be guided along a patient's artery to a target area, for example, the patient's heart, there are major safety concerns about the use of cryosurgical catheters. In order to produce the desired cooling effect, the gas has to be delivered to the probe tip at very high pressure, typically of the order of 5000 KPa (50 bar or approximately 725 psi). On the exhaust side, the pressure is still relatively high, at between 345 and 690 KPa (approximately 50-100 psi). Critical leaks could develop in the wall of the catheter or, more importantly, at the

junction between the catheter and the metal tip. Should such a leak occur, then a significant amount of gas is likely to leak into the patient's venal system or, if the probe is positioned in the heart, the gas will leak into the heart itself. If a leak occurs, this is likely to be catastrophic, leading to the patient's death.

It has been proposed that elaborate sensors be used at the proximal end of the catheter to monitor the rate and pressure of gas delivery and exhaust, in an attempt to detect any leaks. However, it has proved impossible to develop such a system which can detect the presence of existing leaks, or the occurrence of very small leaks, or which can act sufficiently quickly to stop the flow of gas in the event of a ma or leak. The minimum response time is currently about 1 second, which is insufficient to guarantee that any leakage of gas can be contained to a non-fatal level.

One particular problem with Joule-Thompson systems is that the throttling of the high pressure gas produces massive turbulence on both the delivery side (i.e. the upstream side) and the exhaust side (i.e. downstream side) of the catheter system. It is therefore impossible to make instantaneous pressure or flow measurements, and the sensor outputs have to be filtered or averaged to remove the fluctuating components of the signal created by the turbulence. This significantly slows the response of the sensors to detecting changes caused by the leaks.

The present invention has been devised bearing the above problems in mind.

In a first aspect, the invention provides cooling probe apparatus comprising:

a probe tip;

a catheter extending to the probe tip, the catheter including an inlet path for supplying a cooling medium to the probe tip and an exhaust path for carrying exhaust medium from the probe tip; and

pump means coupled to the downstream end of the exhaust path of the catheter to draw the exhaust cryogen through the exhaust path, the pump means being operable to create, under normal operating conditions of the probe, a pressure in the exhaust path at a

point adjacent to the probe tip, said pressure being not significantly greater than the external pressure around the probe tip.

Preferably, the probe is a cryosurgical probe.

Preferably, the probe tip contains a Joule-Thompson cooling arrangement.

The normal operating conditions of the probe include the probe being leak free, and the flow rate of cryogen being within normal operating limits.

The pressure seen at a point in the exhaust path adjacent to the probe tip will generally be very different from the pressure at the end of the exhaust path adjacent to the pump. In particular, the pressure will be affected by the conductance of the catheter, the conductance of the conduits linking the catheter to the pump, and the conductance of any in-line protection filters provided for the pump. The catheter will normally have only a narrow exhaust bore, and may be fairly long, typically up to about 2 metres. There may also be additional narrow bone tubing between the end of the catheter and the pump. As illustrated in the test results described further below, at a flow rate of 40 litres/minute, the pressure drop along the link conduit was measured at about 0.02 bar, and the pressure drop across the filter was measured at about 0.13 bar.

The pressure reduction generated by the pump is likewise affected by the flow rate through the pump, this being a generally inverse relationship such that the pressure reduction increases (improves) as the flow of exhaust cryogen is reduced.

Such apparatus can provide the following advantages over the prior art techniques:

(1) There is very little pressure differential between the exhaust conduit and the external atmosphere, or other surroundings (for example, a person's blood stream) to cause a leak.

(2) Should a leak occur, then since the pressure in the outlet conduit is not significantly greater than the surrounding pressure, there will very little leakage of exhaust cryogen.

Yet further advantages can be achieved if, preferably, the pressure in the outlet conduit at a point adjacent to the probe tip is reduced to a level which is below that of the surrounding pressure. In such case, there is "negative" pressure in the outlet conduit compared to the surroundings. Should a leak occur the tendency will be for fluid surrounding the probe (for example, blood) to leak into the outlet conduit, rather than for any exhaust cryogen to leak out. It will be appreciated that, with this preferred feature, the invention can enable a device such as a cryosurgical catheter to be used inherently safely, rather than as a device which is potentially life threatening should the catheter develop a leak.

Since the invention acts by reducing the pressure in the outlet conduit, it is preferred that the inlet conduit be carried within the outlet conduit. In the event of a leak from the inlet conduit, the high pressure gas will leak into the outlet conduit, in which the gas will be drawn safely away.

Pump devices have previously been proposed, operating at a relatively low rate, to increase the pressure differential at the probe tip between the inlet and exhaust conduits (i.e. to increase the internal pressure differential) and hence to increase the efficiency of the catheter probe. Such a pump is illustrated, for example, in the above-mentioned EP-A-0655225. However, such an arrangement does not provide the same leak-protection as described herein, and does not address the issue of exhaust path pressure at the probe tip compared to external pressure.

Other advantages which can be provided by the pump are as follows:

(c) By reducing the pressure in the outlet conduit, the mechanical strain on the probe tip is reduced, thus reducing the chances of the tip becoming detached from the catheter.

(d) By drawing the exhaust cryogen away, the turbulence in both the inlet and outlet conduits is surprisingly reduced. This enables more accurate and reliable measurements of the gas parameters, such as flow rate and pressure, to be made instantaneously, which thus reduces the response time of any monitoring circuitry.

For example, the occurrence of a leak might be detected by monitoring one or more of the following parameters:

(a) probe tip temperature

(b) exhaust pressure

(c) flow rates of inlet and/or exhaust

(d) liquid presence in exhaust

For parameters (a), (b) and/or (c), it maybe sufficient to detect a change, for example an abrupt change, in the value of parameter, as being indicative of a leak occurring.

The invention also permits parameter (d) to be used, because there may be a tendency for the patient's fluid (e.g. blood) to be sucked into the exhaust path, in view of the pumping of the exhaust path.

In a preferred aspect, the invention provides cryosurgical apparatus comprising:

a probe tip

a catheter extending to the probe tip, the catheter including an inlet path for supplying a cooling medium to the probe tip and an exhaust path for carrying exhaust medium from the probe tip;

pump means coupled to the downstream end of the exhaust path to draw the exhaust medium through the exhaust path; and

means for detecting the occurrence of a leak in the catheter.

The detecting means may comprise means for monitoring one or more operating characteristic of the apparatus, such as for example, the probe tip temperature, the exhaust pressure, the flow rate of the inlet and/or of the exhaust, and the presence of liquid in the exhaust.

The detecting means may be responsive to a sudden change in the operating characteristic, indicative of the occurrence of a leak.

Preferably, the apparatus comprises control means for cutting off the supply of the cooling medium if a leak is detected.

Preferably, the apparatus comprises control means for continuing to operate the pump means for at least a predetermined deviation following the detection of a leak, in order to remove cooling medium from the catheter and from the probe tip.

An embodiment of the invention will now be described by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 illustrates schematically the principles of the present invention in a cryosurgical catheter system;

Fig. 2 is a partial cut-away view of the tip of a cryosurgical catheter;

Fig. 3 is a cross section through the catheter at an intermediate point along the catheter length;

Fig. 4 is a schematic block diagram of a control console for the catheter;

Fig. 5 is a schematic block diagram illustrating a first test arrangement for simulating a catheter failure;

Fig. 6 is a schematic block diagram illustrating a second test arrangement for simulating tip loss failure; and

Fig. 7 is a graph showing the characteristics of the catheter and pump system used in the test arrangements of Figs. 5 and 6.

Referring to Fig. 1, a cryosurgical catheter system includes a catheter 10 having an inner tube 12 mounted within an outer tube 14. Cryogen gas, such as nitrous oxide or carbon dioxide, is supplied from a source 16 through a delivery control valve 18 to the inner tube 12 for supply to the catheter tip 20. The gas is at a high pressure, typically in the region of 600-750 psi. At the tip 20, the inner tube 12 has a Joule-Thompson nozzle 22 (or constriction or other type of orifice) through which the gas is forced, to create cooling. The gas is exhausted through the catheter along an exhaust path 24 between the inner and outer tubes 12 and 14 respectively.

In accordance with the principles of the invention, a pump 26 is connected at the outlet end of the exhaust path 24. The pump 26 draws the exhaust gas away from the tip and out of the exhaust path 24, thereby reducing the gas pressure in the exhaust path 24.

For optimum effect, in this embodiment, the pump has a sufficient capacity, under normal (i.e. leak free) operating conditions, to reduce the pressure in the exhaust path 24 to below the surrounding pressure. In particular, the negative pressure is achieved along the entire length of the exhaust path, such that the pressure adjacent to the probe tip is also negative relative to the external surroundings.

The pressure may be negative relative to ambient atmospheric pressure, or relative to a slightly higher pressure surrounding the probe tip. For example, in a human heart, the pressure is around 100 mm Hg, or about 0.15 bar higher than eternal atmospheric pressure.

In the present embodiment, under normal operating conditions, the rate of cryogen flow through the probe tip is about 8-9 litres a minute; the pump likewise has a capacity of drawing away at least 8 and 9 litres of gas per minute. The pulling or "sucking" pressure of the pump varies with the flow rate, but at the above flow rate is roughly -0.8 bar.

Leaks occurring in the catheter may occur generally in one of three regions. Should a small leak occur in the wall of the delivery conduit (for example, at a point 30), the high pressure gas will leak directly into the exhaust path 24 from which it can be drawn away. If the leak is large (so that the rate of gas flow exceeds the usual 8-9 litres/minute), there will be a noticeable change in gas pressure in the exhaust path 24, and also in the inner tube 12 which can easily be detected by monitoring equipment (as described later).

Should a small leak occur in the wall of the outer tube 14 (for example, either a small leak through the catheter wall or a small leak at the connection to the tip 20, which is particularly vulnerable region), then the negative pressure in the exhaust path (compared to the surrounding pressure) can ensure that no gas will leak out of the tube. The pressure differential may cause body fluid surrounding the catheter (for example, blood) to ingress through the "leak" aperture into the exhaust path 24. However, in the

case of blood which is comparatively viscous and coagulates easily, very little blood (if any) will Pass through the leak aperture unless the aperture is sizeable.

The third type of leak is total detachment of the tip 20 from the catheter 10. This results in a massive end leak. Such a scenario is extremely unlikely because the tip 20 is attached to the catheter inner and outer tubes, and to two control wires (not shown) used to steer the tip when the catheter is guided through the blood vessels. Nevertheless, such a leak is considered here as a worst case leak. Should such a leak occur, then the negative pressure in the exhaust path will at least reduce the rate of flow of cryogen through the leak. The positioning of the orifice 22 relative to the massive end leak may make it difficult to avoid some cryogen escaping at high inlet pressures, but the situation is less critical than if no negative pressure existed in the exhaust path. Such a leak would cause a major pressure change in the exhaust path which could be detected easily to cut off the supply through the catheter.

Referring to Figs. 2 and 3, the configuration of the catheter 10 and its tip 20 are shown in more detail. The tip 20 has a rear extension 34 which fits into the distal end of the catheter outer tube 14, and is secured by adhesive. Although not shown, a security wire, and a catheter steering wire may extend through the catheter and be secured (for example, by crimping or welding) to the tip 20. As explained above, such wires would normally provide additional security in anchoring the tip 20 at the end of the outer tube 12, and preventing the tip 20 from being blown off the tube 12 by the pressure of gas in the catheter.

In the present embodiment, the negative pressure established in the exhaust path 24 further enhances the integrity of the tip catheter by actively "sucking" the tip 20 on to the end of the outer catheter tube 14. Therefore, this further reduces the risk of the catheter tip 20 becoming dislodged from the catheter even in the event of failure of the mechanical fixings, and also reduces the normal operating stresses on the mechanical fixings.

The catheter may also have one or more electrical contacts, in the form of metal bands 36 (two being illustrated in Fig. 2). The electrical contacts may be used either for physiological measurements, or for applying electrical signals such as RF signals to the subject area of the body. A thermocouple or other temperature sensor (illustrated schematically at 38) may be attached to the tip 20 for measuring the temperature at the tip during cooling operation. The electrical signals to and/or from the bands 36 and the temperature sensor 38 are communicated by wires 40 (Fig. 3) contained in a protective insulating sheath 42 received within the outer tube 14.

Referring to Fig. 3, the inner tube 12 and the sheath 42 may be allowed to "float" freely in the outer tube 14. The steering and the anchoring wires (not shown) may either be received within the sheath 42, or extend separately in the interior of the outer tube 14.

Although not shown in the drawings, the catheter system may include a precooling arrangement near the tip (for example, as described in GB-A-2226497) and/or in the catheter handle (for example, as described in GB-A-2283678).

Referring to Fig. 4, a control console 50 is illustrated for controlling cooling operation of the catheter 10. The console 50 includes a front panel 52 presenting the main cryogen gas pressure regulator valve 18, a cryogen gas pressure gauge 56, a catheter (tip) temperature gauge 58, and a catheter connector 60 to which the catheter is removably connected.

Cryogen gas is received from a supply (not shown) connected to an inlet connector 62 coupled to the upstream side of the regulator valve 18. The downstream side of the regulator valve 18 is coupled through an electrically operated vent valve 64 to supply line conduit 66 which supplies gas to the pressure gauge 56 and to the inner tube 12 of the catheter when the catheter 10 is connected to the connector 60. The vent valve 64 enables the pressure in the supply line conduit 66 to be reduced to atmospheric pressure by venting through a vent conduit 68, for example, if the gas flow through the catheter needs to be stopped quickly in the event of an emergency.

An exhaust line conduit 70 extends from the catheter connector 60 through the pump 26 to an exhaust connector 72. When the catheter 10 is connected, the exhaust line conduit 70 is coupled to the exhaust path 24 between the inner and outer catheter tubes 12 and 14, respectively. Although the pump 26 is shown schematically as being located within the console 50, it will be appreciated that the pump could be located downstream of the exhaust connector 72. Additionally, if desired, a medical collection filter/bottle or catch tank (illustrated schematically at 74) may be included in the exhaust line conduit 70 to filter out and collect any body fluid which might be sucked back by the pump 26 in the event of a leak developing in the catheter. The catch tank can provide a visual filter to enable the use to see whether any blood has been sucked into the catheter through a leak aperture. The catch tank may also include a liquid sensor for providing an electronic signal if liquid is detected, indicating a leak has occurred.

If the catheter includes a device for pre-cooling the incoming cryogenic fluid (the device being of a type which diverts a portion of the incoming fluid to cool the remaining fluid flowing to the catheter), then preferably, the precooler exhaust is retained separate from the catheter exhaust fed through the pump. This is to ensure that an optimum negative pressure can be retained in the catheter exhaust path itself (rather than being wastefully applied in the precooler exhaust path).

Although not shown, the catheter connector 60 also includes electrical connections for the wires 40 communicating with the temperature sensor 38 and the metal bands 36.

The console 50 operates under the control of a microprocessor or microcontroller circuit (shown schematically at 76). One or more further sensors may be connected to the circuit 70 for monitoring the performance of the system, and for detecting the occurrence of leaks in the catheter. For example, a flow sensor (shown schematically at 78) may be included in the supply line conduit 66 in addition to the pressure gauge (and sensor) 56. It has been found that by pumping out the exhaust gases from the exhaust path 24, the usual turbulence in the delivery and exhaust paths (created by the throttling

effect of the nozzle 22) can be significantly reduced, enabling more accurate and reliable instantaneous measurements to be made. In particular, it may be possible to monitor the catheter system merely by sensing pressure and flow parameters on the delivery side of the catheter. Additionally, or alternatively, a flow sensor 80 and a pressure sensor 82 may be included in the exhaust path for monitoring the exhaust parameters. If any of the inlet or exhaust parameters should vary outside normal levels, or show an abrupt change in level, this is indicative of a leak which may be too large for the pump 26 to accommodate. Additionally or alternatively, the occurrence of a leak may be detected by monitoring the tip temperature. Should an abrupt change in temperature be detected, this may be indicative of a leak.

In the event of the leak, the circuit 76 controls the vent valve 64 to cut off the supply of cryogen gas, and to vent the supply line conduit 66 to atmospheric pressure. The pump 26 is controlled to continue pumping out cryogen gas from the exhaust path 24 for at least a short time following the venting of the supply line conduit 66, to try to extract any cryogen gas remaining in the catheter. The pump 26 may be controlled to stop either when the pressure in the exhaust path 24 has dropped below a certain level, or after a predetermined interval has elapsed. The negative pressure in the exhaust path should not exceed (negatively) a predetermined "collapsing" threshold, representing the largest negative pressure which the outer catheter tube 14 is able to withstand without collapsing. It will be appreciated that if the catheter tube collapses it may be extremely difficult to withdraw the catheter from the patient, as the flexibility and steerabilty of the catheter may be impaired.

The pump 26 may be any suitable pump, for example a vacuum-type pump (i.e. able to develop a large pumping pressure for a small quantity of gas moved), or a fan type pump (i.e. able to move large quantities of gas, but developing generally a modest pumping pressure).

To analyse the performance of the pump, and to simulate the behaviour of the probe in the event of a leak, a test rig 100 was utilised in two configurations as illustrated

in Figs. 5 and 6. The purpose of the test was to establish whether the invention would be effective in practice, and to establish whether a particular type of pump (having a certain pump rate) would be suitable for a particular catheter arrangement.

In both arrangements, the catheter 10 was coupled to a handle unit 102 including an upstream pre-cooling heat exchanger as described in GB-A-2283678. The handle unit receives incoming cryogen fluid through an inlet line 104 coupled to the main control console (not shown). The exhaust from the catheter 10 was passed through a narrow bore tube 106 coupled through a filter 108 to a suction pump 110. The pressure at the entrance to the pump was measured by a pressure sensor 112, and the flow rate through the pump was measured by a flow meter 114.

Before the failure simulation tests were carried out, the stable characteristics of the catheter and pump system were first determined, and are illustrated in the graph of Fig. 7. The graph shows the variation of the pump inlet pressure with the flow rate through the system. As expected, the degree of pressure reduction increases as the flow rate decreases. At a flow rate of about 40 litres/min, the pressure reduction across the filter was measured to be about 0.13 bar, and the pressure reduction through the pump inlet tube was measured to be about 0.02 bar. This means that the pressure reduction at the probe tip may be expected to be up to about 0.15 bar less than that measured at the pump inlet.

The arrangement illustrated in Fig. 5 was designed to simulate the occurrence of a leak through the catheter wall at a point 120. A small hole of about 0.35mm diameter was drilled through the catheter wall at a distance of about 330mm from the catheter tip. The pressure at the hole (relative to atmospheric pressure) was measured by a pressure gauge 122, and the temperature of the catheter tip was measured by a temperature sensor (thermocouple) 124.

The results of the test are illustrated in TABLE 1 below. The results show that, for supply pressures up to about 45 bar, the pump hole pressure was always negative. In other words, the pressure within the catheter exhaust path was less then the surrounding

atmospheric pressure. Thus, there would be no tendency for gas in the catheter exhaust path to escape through the leak opening into the external surroundings (e.g. a person's blood vessel). On the contrary, the tendency would be for small quantities of blood to be sucked into the catheter.

TABLE 1: PIN HOLE EXPERIMENT

Working Press (Bar)	Hole Press (Bar)	Tip Temp (C)	Pump Press (Bar)	Pump Flow (l/min)
0	-0.79	22	-0.88	3.8
10	-0.773	10.8	-0.88	4
20	-0.64	-5.4	-0.87	5
30	-0.52	-48	-0.85	6
35	-0.47	-73	-0.84	7
40	-0.36	-85	-0.82	8.5
45	0.37	-77	-0.66	16.5

In the present test, when the catheter inlet pressure exceeded about 45 bar, the hole pressure became positive, indicating that gas would begin to escape from the catheter into the external surroundings.

The arrangement illustrated in Fig. 6 was designed to simulate total loss of the tip from the end of the catheter. As explained previously, tip loss is extremely unlikely to occur, and this may be regarded as a worst-case failure situation. As illustrated in Fig. 6, the pressure at the open end of the catheter was measured by pressure sensor 126, and the flow rate through the end of the catheter was measured by a flow meter 128.

The results of the test are illustrated in TABLE 2 below. The results show that for catheter inlet pressures up to about 40 bar, the tip pressure is negative (i.e. relative to atmospheric pressure), and the tip flow rate is zero. Thus, there would be no tendency for

gas to escape through the open tip into the external surroundings (e.g. a person's blood vessel). However, the design of the catheter tip may in practice make it difficult to avoid the leakage of at least some gas in the event of tip loss.

TABLE 2: OPEN TIP EXPERIMENT

Working Press Bar	Tip Press Bar	Tip Flow l/min	Pump Press Bar	Pump Flow l/min
0	-0.65	0	-0.85	5.5
10	-0.5	0	-0.84	6.5
20	-0.35	0	-0.84	7
30	-0.27	0	-0.82	7.5
40	-0.12	0	-0.81	9
50	0.4	4	-0.84	7
45	0.02	3.5	-0.83	6
40	0.008	1	-0.83	7
30	-0.25	0	-0.82	7.5
20	-0.45	0	-0.85	5.5
10	-0.57	0	-0.85	5.5
0	-0.64	0	-0.85	5.5

In the present test, when the catheter inlet pressure exceeded 40 bar, the tip pressure became positive, and flow through the tip flow rate meter 128 became positive. This indicates that gas would begin to escape through the open tip under the particular test conditions used.

The purpose of the tests were to verify the principle of operation, and to identify the characteristics of a particular catheter and pump system. In the tests, gas was found

to leak at high catheter inlet pressures. In practice such leaks can be avoided bearing in mind the following considerations:

(a) The pump used in the test had a relatively modest pumping power. Leaks can be countered even at very high inlet pressures by using a more powerful pump. A suitable pump system can be found using similar tests to those described above.

(b) When used in a patient's blood vessel, or in the heart, the surrounding blood pressure is generally higher than atmospheric pressure, for example, by about 0.1 to 0.2 bar. Thus leaks will not occur unless the gas pressure in the catheter on one side of the leak opening exceeds this higher pressure.

The catheter system described above is especially suitable for cryosurgical applications, involving freezing of tissue. However, neither this embodiment or the invention as a whole is limited exclusively to cryosurgical use. For example, the catheter may be used for physiological heart measurements, in which regions of the heart are cooled (but not frozen) to reduce the nervous activity, and the electrical signals in the heart then measured (for example, using the metal bands 36). The catheter may also be used in RF ablation, in which a radio frequency signal is applied to the heart. One of the problems with conventional RF catheters is that the treatment generates significant heat, which progressively reduces the effectiveness of the RF treatment. It is known that, for optimum effect, the RF signal should be applied over quite a long time interval, but the heating problem has prevented this goal from being realised with conventional equipment. However, with the catheter illustrated above, the tip can provide an additional heat-sink function to cool the heart, and enable the RF treatment to be continued for much longer intervals.

It will be appreciated that the invention is not limited to the forgoing description of a preferred embodiment and that modifications may be made within the scope and/or principles of the invention.

While features and aspects believed to be of importance have been identified in the foregoing specification, the Applicant claims protection for any novel feature or

combination of features described herein and/or illustrated in the drawings irrespective of whether emphasis has been placed thereon.

CLAIMS

1. Cryosurgical apparatus comprising:

a probe tip

a catheter extending to the probe tip, the catheter including an inlet path for supplying a cooling medium to the probe tip and an exhaust path for carrying exhaust medium from the probe tip;

pump means coupled to the downstream end of the exhaust path to draw the exhaust medium through the exhaust path; and

means for detecting the occurrence of a leak in the catheter.

2. Cooling probe apparatus comprising:

a probe tip;

a catheter extending to the probe tip, the catheter including an inlet path for supplying a cooling medium to the probe tip and an exhaust path for carrying exhaust medium from the probe tip; and

pump means coupled to the downstream end of the exhaust path of the catheter to draw the exhaust cryogen through the exhaust path, the pump means being operable to create, under normal operating conditions of the probe, a pressure in the exhaust path at a point adjacent to the probe tip, not significantly greater than the external pressure around the probe tip.

3. Apparatus according to claim 2, further comprising means for detecting the occurrence of a leak.

4. Apparatus according to claim 1 or 3, wherein the means for detecting a leak comprises means for monitoring one or more operating characteristics of the apparatus.

5. Apparatus according to claim 4, wherein a said operating characteristic is the probe tip temperature.

6. Apparatus according to claim 4 or 5, wherein a said operating characteristic is the exhaust pressure.

7. Apparatus according to claim 4, 5 or 6, wherein a said operating characteristic is the inlet flow rate.

8. Apparatus according to claim 4, 5, 6 or 7, wherein a said operating characteristic is the exhaust flow rate.

9. Apparatus according to any of claims 4 to 8, wherein the detecting means comprises means for detecting the presence of liquid in the exhaust medium.

10. Apparatus according to any preceding claim, wherein the pump means is operable to reduce the pressure in the outlet path adjacent to the probe tip to a pressure which is less than said pressure surrounding the tip and/or outlet conduit in use.

11. Apparatus according to any preceding claim, wherein the pump means is operable to reduce the pressure in the outlet path adjacent to the probe tip to a pressure which is less than or about atmospheric pressure.

12. Apparatus according to any preceding claim, wherein said pump means is electrically controllable.

13. Apparatus according to any preceding claim, further comprising a cryogen supply coupled to the inlet path for supplying cryogen thereto.

14. Apparatus according to claim 13, comprising control means operable to terminate the supply of cryogen to the inlet path, and for stopping operation of said means at a later time.

15. Apparatus according to any preceding claim, wherein the inlet path is mounted within the outlet path, at least over part of the lengths of the conduits.

16. Apparatus according to any preceding claim, wherein the catheter is steerable.

17. Apparatus according to any preceding claim, wherein the probe is a Joule Thompson cooled probe.

18. Apparatus according to any preceding claim, wherein the pump means has a capacity to remove exhaust cryogen at a rate greater than the rate at which cryogen is supplied under normal operating conditions of the probe.

19. A method of operating a cooled probe, the method comprising:

supplying cryogen to an inlet path of a catheter probe to cool a tip region of the catheter probe; and

pumping an exhaust path of the probe to draw the exhaust cryogen through the exhaust path, to create, under normal operating conditions of the probe, a pressure in the exhaust path at a point adjacent to the tip region, said pressure being not significantly greater than the external pressure around the probe tip.

20. A method according to claim 19, wherein said pumping reduces the pressure in the outlet path adjacent to the probe tip to a pressure which is less than said pressure surrounding the tip and/or outlet conduit in use.

21. A method according to claim 19 or 20, comprising carrying out the supplying and pumping operations simultaneously for a first time interval.

22. A method according to claim 21, comprising carrying out the pumping operation for a subsequent second time interval without supplying the cryogen.

23. A method according to claim 19, 20, 21 or 22 further comprising monitoring one or more characteristics of the apparatus to detect the occurrence of a leak.

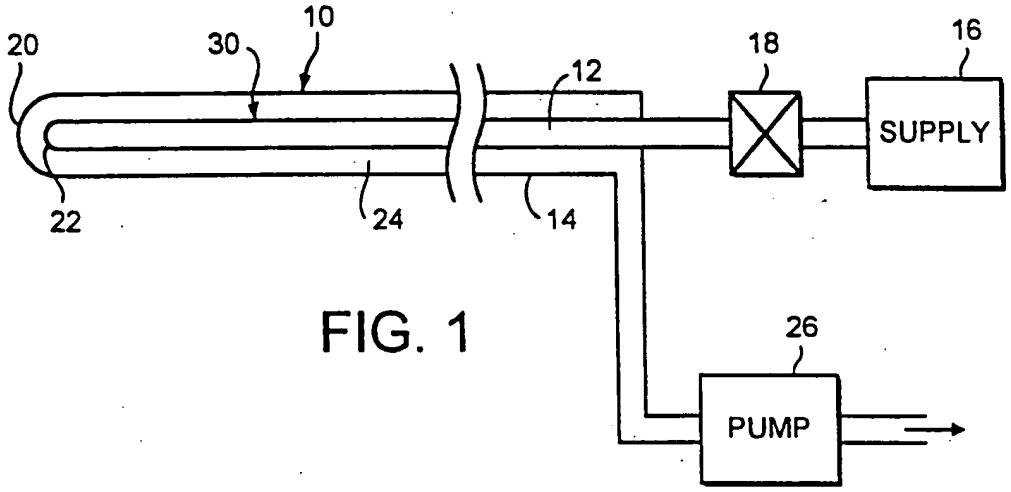


FIG. 1

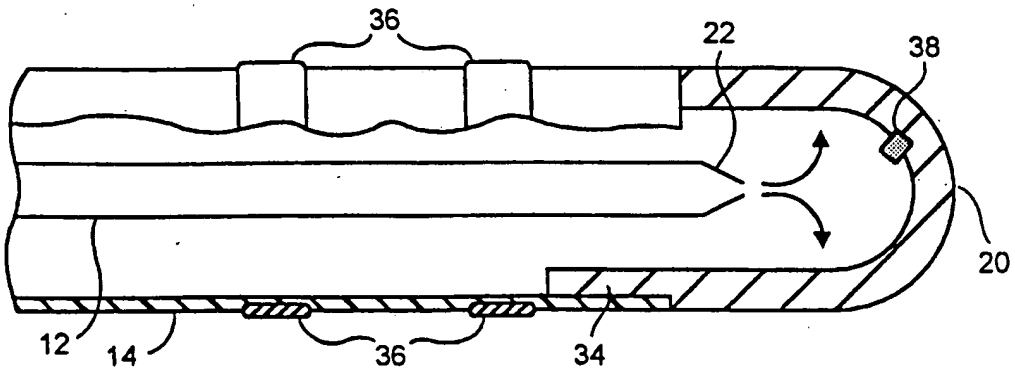
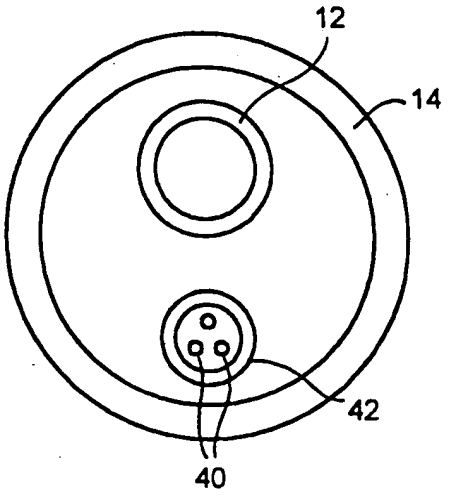


FIG. 2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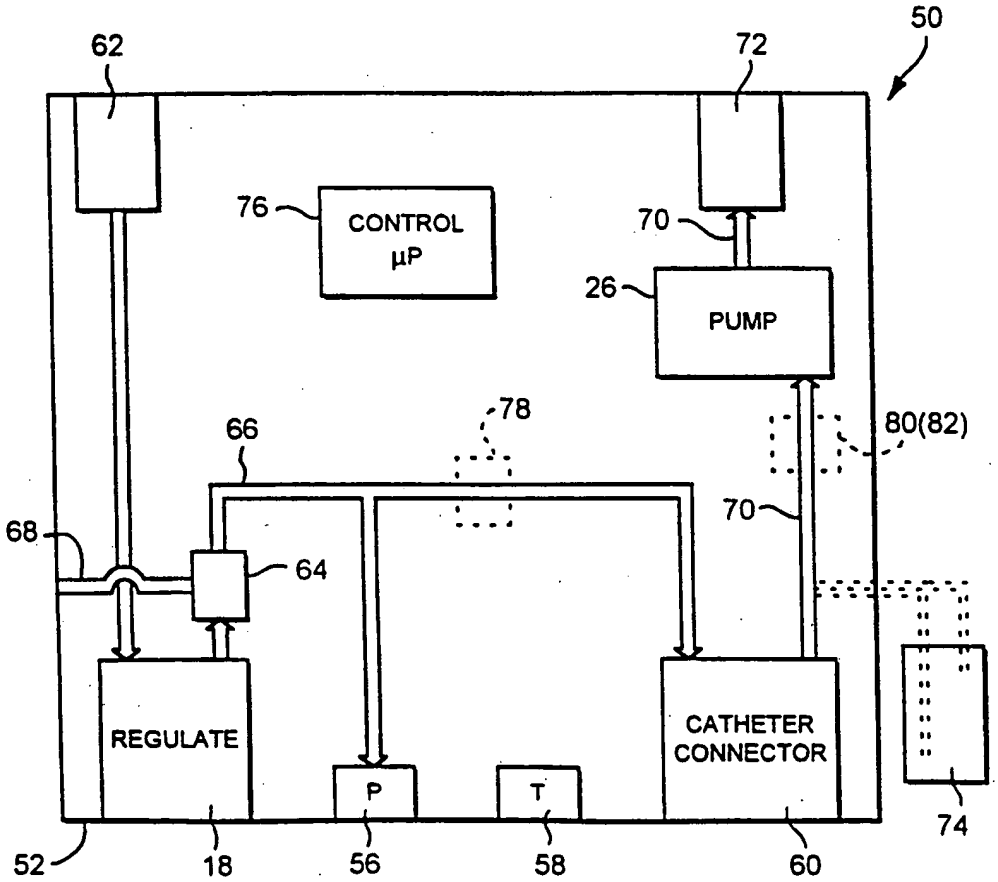
42
40

FIG. 3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62
72
76
CONTROL
µP
70
26
PUMP
78
66
80(82)
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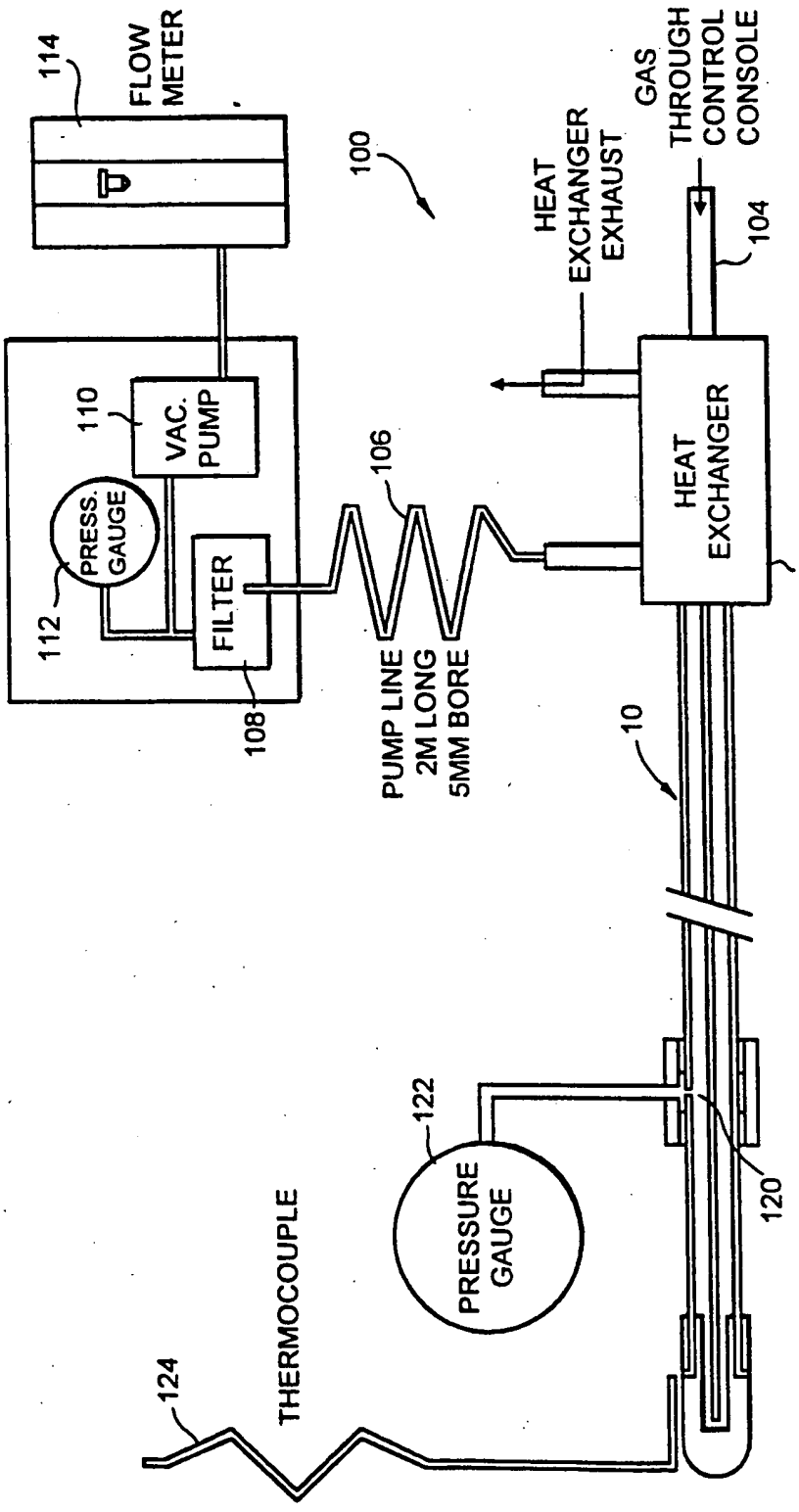
68
64
REGULATE
P
T
CATHETER
CONNECTOR
74
52
18
56
58
60

FIG. 4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FLOW METER
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GAS THROUGH CONTROL CONSOLE
104
110
VAC. PUMP
106
HEAT EXCHANGER
102
PRESS. GAUGE
112
FILTER
108
PUMP LINE 2M LONG 5MM BORE
10
122
PRESSURE GAUGE
120
THERMOCOUPLE
124

FIG. 5

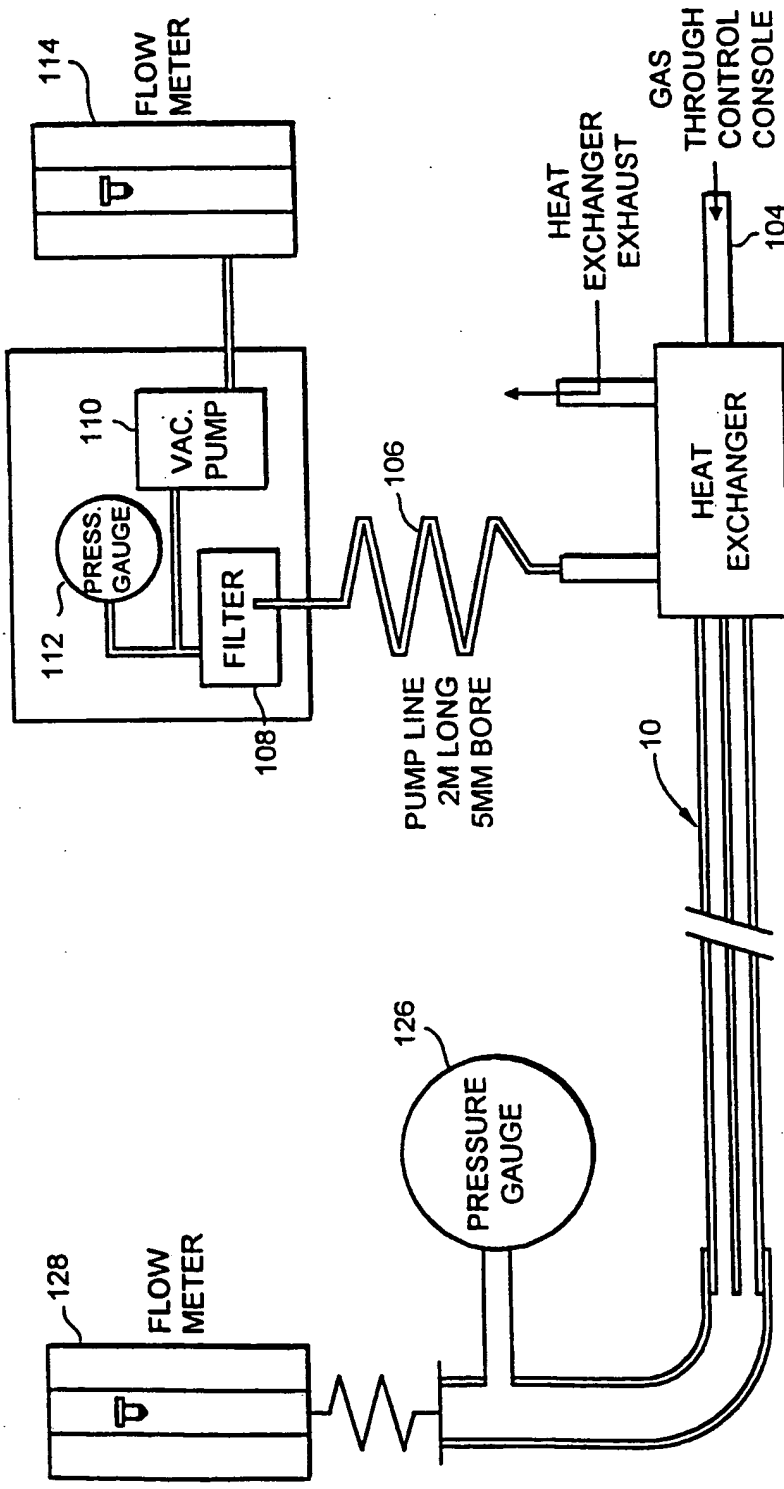
114
FLOW METER
HEAT EXCHANGER EXHAUST
GAS THROUGH CONTROL CONSOLE
104
110
VAC. PUMP
106
HEAT EXCHANGER
102
PRESS. GAUGE
112
FILTER
108
PUMP LINE 2M LONG 5MM BORE
10
126
PRESSURE GAUGE
128
FLOW METER

FIG. 6

INTERNATIONAL SEARCH REPORT

In. .tional Application No
PCT/GB 99/01351

A. CLASSIFICATION OF SUBJECT MATTER

A 61 B 17/36

According to International Patent Classification (IPC) or to both national classification and IPC 6

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A 61 B,A 61 F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where approoriate, of the relevant passages	Relevant to claim No.
Y	US 3536075 A (THOMAS, E.R., JR.) 27 October 1970, the whole document, column 2, line 35 - column 3, line 33.	2,10, 11,13-15,17, 19-21
A		1,12, 18,22, 23
	--	
Y	DE 1278068 B (CHATO, J.) 19 September 1968, the whole document, especially column 8, lines 44-53, fig. 10.	2,11, 13-15, 17,19-21
A		1,4,5, 18,22, 23
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[X] Further documents are listed in the continuation of box C.

[ ] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
09 August 1999	28 SEP 1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	NARDAI e.h.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int. onal Application No
PCT/GB 99/01351

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE 2247092 A (DRÄGERWERK AG) 04 April 1974, page 1, paragraph 3 - page 3, line 1, especially page 2, last paragraph. --	2,10, 13,15, 17,19, 20
A	WO 95/30380 A2 (SPEMBLY MED. LTD.) 16 November 1995, the whole document, especially page 11, line 14 - page 12, line 13. --	1,2,4-6,17, 19,23
A	DE 2332513 B2 (OKADA, J. et al.) 10 July 1975, the whole document, especially column 3, lines 39-49, column 4, lines 6-17, 48-51 (cited in the application). --	1,2, 16,17, 19
A	GB 2283678 A (SPEMBLY MED. LTD.) 17 May 1995, the whole document, especially abstract, page 9, lines 30 - page 10, lines 24 (cited in the application). --	1,2,4, 5,16, 17,19
A	US 5078713 A (VARNEY, K.J.) 07 January 1992, the whole document (cited in the application). --	1,2, 16,17, 19
A	EP 0655225 A1 (CORDIS EUROPA N.V.) 31 May 1995, the whole document. ----	1,2,4, 5,17, 19

INTERNATIONAL SEARCH REPORT

Int. onal Application No
PCT/GB 99/01351

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE 2247092 A (DRÄGERWERK AG) 04 April 1974, page 1, paragraph 3 - page 3, line 1, especially page 2, last paragraph. --	2,10, 13,15, 17,19, 20
A	WO 95/30380 A2 (SPEMBLY MED. LTD.) 16 November 1995, the whole document, especially page 11, line 14 - page 12, line 13. --	1,2,4-6,17, 19,23
A	DE 2332513 B2 (OKADA, J. et al.) 10 July 1975, the whole document, especially column 3, lines 39-49, column 4, lines 6-17, 48-51 (cited in the application). --	1,2, 16,17, 19
A	GB 2283678 A (SPEMBLY MED. LTD.) 17 May 1995, the whole document, especially abstract, page 9, lines 30 - page 10, lines 24 (cited in the application). --	1,2,4, 5,16, 17,19
A	US 5078713 A (VARNEY, K.J.) 07 January 1992, the whole document (cited in the application). --	1,2, 16,17, 19
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ANHANG

zum internationalen Recherchenbericht über die internationale Patentanmeldung Nr.

ANNEX

to the International Search Report to the International Patent Application No.

ANNEXE

au rapport de recherche international relatif à la demande de brevet international n°

PCT/GB 99/01351 SAE 233004

In diesem Anhang sind die Mitglieder der Patentfamilien der in obengenannten internationalen Recherchenbericht angeführten Patentdokumente angegeben. Diese Angaben dienen nur zur Unterrichtung und erfolgen ohne Gewähr.

This Annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The Office is in no way liable for these particulars which are given merely for the purpose of information.

La présente annexe indique les membres de la famille de brevets relatifs aux documents de brevets cités dans le rapport de recherche international visée ci-dessus. Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office.

In Recherchenbericht angeführtes Patentdokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
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